

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

IN RE: VALSARTAN, LOSARTAN, AND IRBESARTAN PRODUCTS LIABILITY LITIGATION	MDL No. 2875 HON. ROBERT B. KUGLER CIVIL NO. 19-2875 (RBK)
THIS DOCUMENT RELATES TO ALL CASES	

**CERTIFICATION OF ADAM M. SLATER IN SUPPORT OF
PLAINTIFFS' MOTION FOR PARTIAL SUMMARY JUDGMENT**

ADAM M. SLATER, hereby certify as follows:

1. I am an attorney at law within the State of New Jersey and a partner with the law firm of Mazie Slater Katz & Freeman, LLC, and serve as Plaintiffs' Co-Lead Counsel. I am fully familiar with the facts and circumstances of these actions. I make this Certification in support of Plaintiffs' motion for partial summary judgment.
2. Attached hereto as **Exhibit 1** is a true and accurate copy of the transcript of Jun Du's May 27, 2021 deposition.
3. Attached hereto as **Exhibit 2** is a true and accurate copy of the transcript of Hai Wang's March 10, 2021 deposition.
4. Attached hereto as **Exhibit 3** is a true and accurate copy of ZHP00079956.

5. Attached hereto as **Exhibit 4** is a true and accurate copy of PRINSTON00012473.

6. Attached hereto as **Exhibit 5** is a true and accurate copy of ZHP01303141.

7. Attached hereto as **Exhibit 6** is a true and accurate copy of ZHP02614594.

8. Attached hereto as **Exhibit 7** is a true and accurate copy of the FDA's Orange Book.

9. Attached hereto as **Exhibit 8** is a true and accurate copy of Health Canada's *Impurities found in certain angiotensin II receptor blocker (ARB) products, also known as sartans* (Apr. 29, 2019), <https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/information-health-product/drugs/angiotensin-receptor-blocker.html>.

10. Attached hereto as **Exhibit 9** is a true and accurate copy of Novartis Pharmaceuticals Corporation (Novartis) Statement on Recall Outside the United States of Sandoz Generic Valsartan and Sandoz Valsartan and Hydrochlorothiazide Film-Coated Tablets (Jul. 16, 2018), <https://www.novartis.com/us-en/news/novartis-pharmaceuticals-corporation-novartis-statement-recall-outside-united-states-sandoz-generic-valsartan-and-sandoz-valsartan-and-hydrochlorothiazide-film-coated-tablets>.

11. Attached hereto as **Exhibit 10** is a true and accurate copy of PRINSTON00075797.

12. Attached hereto as **Exhibit 11** is a true and accurate copy of the transcript of Min Li's April 20, 2021 deposition.

13. Attached hereto as **Exhibit 12** is a true and accurate copy of ZHP01843066.

14. Attached hereto as **Exhibit 13** is a true and accurate copy of PRINSTON00162349.

15. Attached hereto as **Exhibit 14** is a true and accurate copy of ZHP00004352.

16. Attached hereto as **Exhibit 15** is a true and accurate copy of ZHP02364173.

17. Attached hereto as **Exhibit 16** is a true and accurate copy of the transcript of Minli Zhang's March 26, 2021 deposition.

18. Attached hereto as **Exhibit 17** is a true and accurate copy of ZHP00683571.

19. Attached hereto as **Exhibit 18** is a true and accurate copy of Zhang 189.

20. Attached hereto as **Exhibit 19** is a true and accurate copy of USP's General Notices and Requirements.

21. Attached hereto as **Exhibit 20** is a true and accurate copy of an excerpt regarding USP Pharmacists' Pharmacopeia on USP's General Notices and Requirements

22. Attached hereto as **Exhibit 21** is a true and accurate copy of the transcript of Eric Gu's April 6, 2021 deposition.

23. Attached hereto as **Exhibit 22** is a true and accurate copy of the transcript of Min Li's April 21, 2021 deposition.

24. Attached hereto as **Exhibit 23** is a true and accurate copy of ZHP00079913.

25. Attached hereto as **Exhibit 24** is a true and accurate copy of ZHP's translation of ZHP00190573.

26. Attached hereto as **Exhibit 25** is a true and accurate copy of ZHP00061069.

27. Attached hereto as **Exhibit 26** is a true and accurate copy of ZHP00061068.

28. Attached hereto as **Exhibit 27** is a true and accurate copy of ZHP00061080.

29. Attached hereto as **Exhibit 28** is a true and accurate copy of ZHP01344159.

30. Attached hereto as **Exhibit 29** is a true and accurate copy of the transcript of Jun Du's May 28, 2021 deposition.

31. Attached hereto as **Exhibit 30** is a true and accurate copy of the transcript of Jucai Ge's May 26, 2022 deposition.

32. Attached hereto as **Exhibit 31** is a true and accurate copy of the transcript of Eric Gu's April 5, 2021 deposition.

33. Attached hereto as **Exhibit 32** is a true and accurate copy of the transcript of Qiangming Li's April 14, 2021 deposition.

34. Attached hereto as **Exhibit 33** is a true and accurate copy of ZHP01748896.

35. Attached hereto as **Exhibit 34** is a true and accurate copy of ZHP01748905.

36. Attached hereto as **Exhibit 35** is a true and accurate copy of the transcript of Qiangming Li's April 15, 2021 deposition.

37. Attached hereto as **Exhibit 36** is a true and accurate copy of ZHP00405069.

38. Attached hereto as **Exhibit 37** is a true and accurate copy of ZHP01313866.

39. Attached hereto as **Exhibit 38** is a true and accurate copy of ZHP02630924.

40. Attached hereto as **Exhibit 39** is a true and accurate copy of ZHP02630926.

41. Attached hereto as **Exhibit 40** is a true and accurate copy of ZHP00496153.

42. Attached hereto as **Exhibit 41** is a true and accurate copy of ZHP00496155.

43. Attached hereto as **Exhibit 42** is a true and accurate copy of ZHP02118712.

44. Attached hereto as **Exhibit 43** is a true and accurate copy of ZHP02094739.

45. Attached hereto as **Exhibit 44** is a true and accurate copy of ZHP00405021.

46. Attached hereto as **Exhibit 45** is a true and accurate copy of the transcript of Qiangming Li's April 13, 2021 deposition.

47. Attached hereto as **Exhibit 46** is a true and accurate copy of the transcript of Peng Dong's March 29, 2021 deposition.

48. Attached hereto as **Exhibit 47** is a true and accurate copy of the transcript of Peng Dong's March 30, 2021 deposition.

49. Attached hereto as **Exhibit 48** is a true and accurate copy of the transcript of Peng Dong's March 31, 2021 deposition.

50. Attached hereto as **Exhibit 49** is a true and accurate copy of Shandong Hualu-Hengsheng Chem Co., *Certification of Analysis for N,H-Dimethylformamide*.

51. Attached hereto as **Exhibit 50** is a true and accurate copy of Zhejiang Jianye Chemical Co., Ltd.'s *Certificate of Analysis for Triethylamine*.

52. Attached hereto as **Exhibit 51** is a true and accurate copy of the transcript of Min Li's April 22, 2021 deposition.

53. Attached hereto as **Exhibit 52** is a true and accurate copy of Minli Zhang's CV (ZHP 162).

54. Attached hereto as **Exhibit 53** is a true and accurate copy of the transcript of Minli Zhang's March 22, 2021 deposition.

55. Attached hereto as **Exhibit 54** is a true and accurate copy of the transcript of Minli Zhang's March 24, 2021 deposition.

56. Attached hereto as **Exhibit 55** is a true and accurate copy of the transcript of Remonda Gergis' February 2, 2021 deposition.

57. Attached hereto as **Exhibit 56** is a true and accurate copy of the transcript of David Chesney's March 21, 2022 deposition.

58. Attached hereto as **Exhibit 57** is a true and accurate copy of Chesney, *Executive Responsibility for Quality* (FDA News 2018).

59. Attached hereto as **Exhibit 58** is a true and accurate copy of ZHP00400220.

60. Attached hereto as **Exhibit 59** is a true and accurate copy of ZHP00400281.

61. Attached hereto as **Exhibit 60** is a true and accurate copy of ZHP00400236.

62. Attached hereto as **Exhibit 61** is a true and accurate copy of PRINSTON00000019.

63. Attached hereto as **Exhibit 62** is a true and accurate copy of PRINSTON00000005.

64. Attached hereto as **Exhibit 63** is a true and accurate copy of PRINSTON00000011.

65. Attached hereto as **Exhibit 64** is a true and accurate copy of ZHP01451842.

66. Attached hereto as **Exhibit 65** is a true and accurate copy of USP's PowerPoint on Impurities in Drug Products and Drug Substances - A USP Approach.

67. Attached hereto as **Exhibit 66** is a true and accurate copy of USP's FAQ: Organic Impurities, <https://www.usp.org/frequently-asked-questions/organic-impurities>.

68. Attached hereto as **Exhibit 67** is a true and accurate copy of PRINBURY00058078.

69. Attached hereto as **Exhibit 68** is a true and accurate copy of PRINBURY00058083.

70. Attached hereto as **Exhibit 69** is a true and accurate copy of PRINSTON00037968.

71. Attached hereto as **Exhibit 70** is a true and accurate copy of PRINSTON00183155.

72. Attached hereto as **Exhibit 71** is a true and accurate copy of PRINSTON00177677.

73. Attached hereto as **Exhibit 72** is a true and accurate copy of ZHP01713711.

74. Attached hereto as **Exhibit 73** is a true and accurate copy of ZHP00073102.

75. Attached hereto as **Exhibit 74** is a true and accurate copy of HUAHAI-US00007752.

76. Attached hereto as **Exhibit 75** is a true and accurate copy of PRINSTON00080011.

77. Attached hereto as **Exhibit 76** is a true and accurate copy of PRINSTON00079747.

78. Attached hereto as **Exhibit 77** is a true and accurate copy of PRINSTON00071532.

79. Attached hereto as **Exhibit 78** is a true and accurate copy of the transcript of Hai Wang's March 11, 2021 deposition.

80. Attached hereto as **Exhibit 79** is a true and accurate copy of the transcript of John Iozzia's January 20, 2021 deposition.

81. Attached hereto as **Exhibit 80** is a true and accurate copy of PRINSTON00000001.

82. Attached hereto as **Exhibit 81** is a true and accurate copy of Teva-230.

83. Attached hereto as **Exhibit 82** is a true and accurate copy of the transcript of Michelle Osmian's May 6, 2021 deposition.

84. Attached hereto as **Exhibit 83** is a true and accurate copy of TEVA-MDL2875-00324735.

85. Attached hereto as **Exhibit 84** is a true and accurate copy of TORRENT-MDL2875-00072650.

86. Attached hereto as **Exhibit 85** is a true and accurate copy of the transcript of Sushil Jaiswal's June 4, 2021 deposition.

87. Attached hereto as **Exhibit 86** is a true and accurate copy of ZHP02592303.

88. Attached hereto as **Exhibit 87** is a true and accurate copy of ZHP01495187.

89. Attached hereto as **Exhibit 88** is a true and accurate copy of ZHP00097775.

90. Attached hereto as **Exhibit 89** is a true and accurate copy of ZHP00097777.

91. Attached hereto as **Exhibit 90** is a true and accurate copy of ZHP-225.

92. Attached hereto as **Exhibit 91** is a true and accurate copy of ZHP's Stipulation, dated May 13, 2022.

93. Attached hereto as **Exhibit 92** is a true and accurate copy of Gomm W, Röthlein C, Schüssel K, Brückner G, Schröder H, Heß S, Frötschl R, Broich K, Haenisch B. *N-Nitrosodimethylamine-Contaminated Valsartan and the Risk of Cancer—A Longitudinal Cohort Study Based on German Health Insurance Data*. Dtsch Arztebl Int. 2021 May 28;118(21):357-362. doi: 10.3238/arztebl.m2021.0129. PMID: 34247699; PMCID: PMC8372009.

94. Attached hereto as **Exhibit 93** is a true and accurate copy of the transcript of Own McMahon's September 23, 2021 deposition.

95. Attached hereto as **Exhibit 94** is a true and accurate copy of the transcript of Jogn Holderman's October 1, 2021 deposition.

96. Attached hereto as **Exhibit 95** is a true and accurate copy of the transcript of Cesar Cedeno's September 27, 2021 deposition.

97. Attached hereto as **Exhibit 96** is a true and accurate copy of the transcript of Catherine Stimmel's September 20, 2021 deposition.

98. Attached hereto as **Exhibit 97** is a true and accurate copy of PRINSTON00035229.

99. Attached hereto as **Exhibit 98** is a true and accurate copy of PRINSTON00065545.

100. Attached hereto as **Exhibit 99** is a true and accurate copy of PRINSTON00032437.

101. Attached hereto as **Exhibit 100** is a true and accurate copy of PRINSTON00248665.

102. Attached hereto as **Exhibit 101** is a true and accurate copy of PRINSTON00141349.

103. Attached hereto as **Exhibit 102** is a true and accurate copy of the relevant excerpts of *IARC Monographs on the Evaluation of the Carcinogenic Risks to Humans: Over Evaluations of Carcinogenicity* (WHO 1987).

104. Attached hereto as **Exhibit 103** is a true and accurate copy of Liteplo, Meek, and Windle, *N-Nitrosodimethylamine: Concise International Chemical Assessment Document 38* (WHO 2002).

105. Attached hereto as **Exhibit 104** is a true and accurate copy of a relevant excerpt of USP's PowerPoint on SUMMARY, HIGHLIGHTS and TIMELINE of GENERAL CHAPTER <1469> NITROSAMINE IMPURITIES.

106. Attached hereto as **Exhibit 105** is a true and accurate copy of EPA, *N-Nitrosodimethylamine*, https://iris.epa.gov/ChemicalLanding/&substance_nmbr=45.

107. Attached hereto as **Exhibit 106** is a true and accurate copy of EPA, *N-Nitrosodiethylamine*, https://iris.epa.gov/ChemicalLanding/&substance_nmbr=42.

108. Attached hereto as **Exhibit 107** is a true and accurate copy of the FDA's Orange Book Preface, <https://www.fda.gov/drugs/development-approval-process-drugs/orange-book-preface>.

109. Attached hereto as **Exhibit 108** is a true and accurate copy of ZHP-296, Plaintiffs' English translation of ZHP00190573.

110. Attached hereto as **Exhibit 109** is a true and accurate copy of ZHP00190573.

111. Attached hereto as **Exhibit 110** is a true and accurate copy of ZHP00367403.

112. Attached hereto as **Exhibit 111** is a true and accurate copy of ZHP-6.

113. Attached hereto as **Exhibit 112** is a true and accurate copy of ZHP-7.

114. Attached hereto as **Exhibit 113** is a true and accurate copy of ZHP-9.

115. Attached hereto as **Exhibit 114** is a true and accurate copy of the transcript of Jie Wang's May 19, 2021 deposition.

116. Attached hereto as **Exhibit 115** is a true and accurate copy of TORRENT-MDL2875-00003964.

117. Attached hereto as **Exhibit 116** is a true and accurate copy of TORRENT-MDL2875-00002185.

118. Attached hereto as **Exhibit 117** is a true and accurate copy of the transcript of Jie Wang's May 18, 2021 deposition

119. Attached hereto as **Exhibit 118** is a true and accurate copy of SOLCO00024231.

120. Attached hereto as **Exhibit 119** is a true and accurate copy of SOLCO00024226.

121. Attached hereto as **Exhibit 120** is a true and accurate copy of PRINSTON00076100.

122. Attached hereto as **Exhibit 121** is a true and accurate copy of ZHP 255.

123. Attached hereto as **Exhibit 122** is a true and accurate copy of ZHP01447235.

124. Attached hereto as **Exhibit 123** is a true and accurate copy of the transcript of Jucai Ge's May 27, 2022 deposition.

MAZIE SLATER KATZ & FREEMAN, LLC
Attorneys for Plaintiffs

By: /s/ Adam M. Slater

Dated: December 22, 2023